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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/585,491	01/05/96	LEE S	220232/1220

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CUSHMAN DARBY & CUSHMAN
1100 NEW YORK AVENUE NW
NINTH FLOOR EAST TOWER
WASHINGTON DC 20005-3918

EXAMINER	
ALLEN, M	

ART UNIT	PAPER NUMBER
1818	

DATE MAILED: 05/07/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1-File Copy

PTO-90C (REV. 2/95)

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Office Action Summary

Application No.	Applicant(s)
08/583,491	Lee
Examiner	**Group Art Unit**
Marianne P. Allen	1818

☒ Responsive to communication(s) filed on *Feb 12, 1997*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *3, 11-15, 22, and 23* is/are pending in the application.

Of the above, claim(s) *23* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *3, 11-15, and 22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *3, 11-15, 22, and 23* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 3, 11-15, and 22 are under consideration by the Examiner. Claim 23 is withdrawn from further consideration as being drawn to a non-elected invention.

Claims 3, 11-15, and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record and as set forth below.

It is noted that applicant admits that the description of recombinant production of GDF-1 in the specification and the description of Figure 9 is insufficient. Applicant's arguments rely upon the assertion in the specification that one could recombinantly produce the protein and the ability of one of ordinary skill in the art to produce the protein at the time of the invention using conventional techniques. As the record does not reflect that any particular difficulties were associated with producing GDF-1, this portion of the rejection is withdrawn with respect to claim 15.

With respect to the "how to use" portion of the rejection, applicant is now arguing that there are uses for the claimed invention disclosed in the specification other than those discussed in the previous Office actions (and not enabled as set forth in the previous Office actions). Because applicant has not argued that the uses discussed in the previous Office actions are enabled, this is viewed as an admission that the examiner's position is correct and that these uses are not enabled.

Applicant is reminded that the first paragraph of 35 U.S.C. 112 states (emphasis added):

> The specification shall contain a **written description** of the invention, and **of the manner and process of making and using it**, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

That is, the specification is required to clearly state how the claimed invention is to be used. It should be apparent to one of ordinary skill in the art how the claimed invention is to be used after reading the specification. One of ordinary skill in the art should not have to envision, infer, or "dream up" potential uses.

Applicant points to the statement on page 12, lines 20-23, "one potential use for GDF-1 as a diagnostic tool is as a specific marker for the presence of tumors arising from cell types that normally express GDF-1." Use as a diagnostic tool for tumors is not enabled as set forth in the prior Office actions. (Note page 14, lines 30-37, which states "the specific clinical settings in which GDF-1 will be used as a diagnostic...await further characterization...") However, applicant asserts that this statement is a generalized statement of use of GDF-1 as a lineage marker for normal tissues. This is not persuasive. A fair reading of this statement would not convey this concept to one of ordinary skill in the art. Applicant provides no support for the statement that "the skilled artisan would understand that this can be generalized to the use..." Applicant has not explained why the skilled artisan would interpret an assertion of diagnostic use for tumors to mean something different.

Applicant then points to Example 4 (starting at page 23) and Figure 6 for use to determine "a cell's embryonic stage and the action of growth and differentiation on the developing embryo

or in cell cultures." First of all, it is not known what is meant by "a cell's embryonic stage." A cell does not have an embryonic stage. A cell has a developmental stage as does an embryo and an embryo is made up of cells. It is further noted that the example and figure make no such assertions of such a use and a fair reading of this example would not convey this concept to one of ordinary skill in the art. At best, a fair reading of the these portions of the specification would provide a tenuous, implied statement of use for the actual GDF-1 DNA sequence (but not degenerate sequences, vectors, host cells, or methods of producing the protein) as a probe for embryo stage or particular tissues identified.

Applicant's arguments with respect to antibodies are not persuasive. While the application discloses production of antibodies, the stated use of these antibodies is not disclosed for "detection of protein to determine temporal- or tissue-specific expression of GDF-1." A fair reading of the specification would not convey this concept to one of ordinary skill in the art. As such, the specification fails to enable how to use the vectors, host cells, degenerate nucleic acid sequences, and methods of producing the protein.

Applicant's arguments with respect to In re Marzocchi, 169 USPQ 367 are missplaced. In this case, there is no statement of use in the specification such as those alleged in the response (tissue markers, temporal- or tissue-specific markers) to dispute. Those specific statements of use that do occur in the specification have been addressed in the prior Office actions as to the reasons to doubt the objective truth of these uses.

Applicant is improperly attempting to add statements of usefulness to the disclosure of the application as filed. See In re Kirk and Petrow, 153 USPQ 48, 53. Applicant has not informed those skilled in the art how to use the claimed invention. See In re Gardner, 166 USPQ 138, 141.

Claims 3, 11-15, and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites "sequence of Figure 2 or Figure 11A or Figure 11B." However, there are two amino acid sequences in each of Figures 11A and 11B. It is unclear what is intended.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hoben et al. was published well after the effective filing date of the instant application and indicates that biological activity, and assays therefore, for GDF-1 had not been determined at the time of the invention.

The examiner is aware of no art that establishes the biological activity of GDF-1.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached on (703) 308-4310. The most convenient FAX telephone number for this examiner is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800